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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

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Applicant's or agent's file reference DELE/P27752PC	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/GB 03/00119	International filing date *(day/month/year)* 14.01.2003	Priority date *(day/month/year)* 15.01.2002
International Patent Classification (IPC) or both national classification and IPC C07B57/00		
Applicant DELTA BIOTECHNOLOGY LIMITED		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
04.08.2003	06.04.2004
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Bedel, C Telephone No. +49 89 2399-2506

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB 03/00119

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-33 as originally filed

Claims, Numbers

1-24 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	
	No:	Claims	1-24
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-24
Industrial applicability (IA)	Yes:	Claims	1-24
	No:	Claims	

2. Citations and explanations

see separate sheet

Novelty

D1-D4 disclose processes for the separation of enantiomers thanks to the use of serum albumin which is always specified as being purified ("99% pure, globulin free or/and fatty-acid free"). Some of the documents also mention the serum albumin as being immobilized on a chromatography column, in particular for HPLC.
The document retrieved on Internet is the exact composition of a Sygma-Aldrich referenced product A3782 used in D1. This product shows a fatty acid content of 0,005% and is globulin free.
Therefore the subject-matter of claims 1-24 cannot be considered as novel over D1-D4.

Inventive step

Should the applicant overcome the novelty objection, it is not certain that the inventive step can be acknowledged.
The technical problem that the present application intends to solve is to "lower the levels of variability between columns" (p.33, l.25-26), the solution being the use of a "highly homogeneous serum albumin".
However, it is considered by the present authority that the use of purer chemicals in a separation process so as to get less erratic results comes within the scope of the customary practice followed by persons skilled in the art, especially as the advantages thus achieved can be readily contemplated in advance.
In the present case, a skilled person observing a difference between the chromatography columns would try first to purify the protein ligand because this is the most obvious source of erratic results, considering the complexity of the serum albumin protein. As long as the "levels of variability between columns" technical problem is concerned, the use of a purified serum albumin is a "one-way street" solution and no inventive skill is necessary to arrive at that solution.
Consequently, the subject-matter of claims 1-24 cannot be considered as involving an inventive step.

Since the technical problem of "affording higher levels of enantioselectivity" is not really proven in the present application (by the means of comparative results with commercial albumin already used in D1-D4, for instance), it cannot be considered as solved, which leads again to a lack of inventive step.